

We claim:

1. A shaped particle for use in treating a bone deficiency wherein said particle is shaped for use in an array of particles interlocked with one another, comprising:
5 a center portion; and
at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one
10 said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array.

2. The particle of Claim 1 wherein at least three of said extremities lie in a plane.

15 3. The particle of Claim 1 wherein said particle has six extremities.

4. The particle of Claim 1 wherein said particle is comprised of a material selected from the group consisting of ceramic, bioactive glass, polymer, polymer/ceramic composite, and polymer/glass composite.

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A1 5.

The particle of Claim 1 wherein said ceramic is comprised of a calcium salt.

6. The particle of Claim 5 wherein said calcium salt is selected from the group consisting of calcium sulfate, calcium carbonate, calcium phosphate and calcium
25 tartarate.

7. The particle of Claim 6 wherein said particle is comprised of calcium sulfate.

8. The particle of Claim 7 wherein said calcium sulfate is in the form of gypsum.

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9. The particle of Claim 6 wherein said particle is comprised of bioactive glass.

10. The particle of Claim 4 wherein said particle is comprised of a polymer.

5 11. The particle of Claim 10 wherein said polymer is selected from the group consisting of polypropylene, polylactic acid, polyglycolic acid and polycaprolactone.

12. The particle of Claim 4 wherein said particle is comprised of a polymer/ceramic composite.

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13. The particle of Claim 4 wherein said particle is comprised of a polymer/glass composite.

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14. The particle of Claim 1 wherein said particle has a diameter of about 3-10 millimeters.

15. The particle of Claim 1 wherein said particle has a diameter of about 4-8 millimeters.

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16. The particle of Claim 1 wherein said particle has a diameter of about 6 millimeters.

17. The array of Claim 1 wherein said array contains multiple particles.

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18. The array of Claim 17 wherein said multiple particles are in a mixture of particles comprised of different materials.

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19. The particles of Claim 18 wherein said different materials are selected from the group consisting of ceramic, calcium salt, bioactive glass, polymer, polymer/ceramic composite, and polymer/glass composite.

20. The particle of Claim 1 wherein said treatment of a bone deficiency is selected from the group consisting of augmentation of bone, repair of bone, replacement of bone, improvement of bone, strengthening of bone and healing of bone.

5 21. The bone deficiency of Claim 20 wherein said bone deficiency is selected from the group consisting of a fracture, break, loss of bone, weak bone, brittle bone, hole in bone, void in bone, disease of bone and degeneration of bone.

10 22. The disease of Claim 21 wherein said disease is selected from the group consisting of osteoporosis, Paget's disease, fibrous dysplasia, osteodystrophia, periodontal disease, osteopenia, osteopetrosis, primary hyperparathyroidism, hypophosphatasia, fibrous dysplasia, osteogenesis imperfecta, myeloma bone disease and bone malignancy.

15 23. The array of Claim 1 wherein said interlocking of said adjacent particles in said array provides adequate porosity to allow ingrowth from a host bone.

20 24. The array of Claim 23 wherein said porosity is between about 40% and about 80%.

25 25. The array of Claim 23 wherein said porosity is between about 60% and about 80%.

26. An array of shaped particles wherein said array comprises a plurality of shaped particles, said shaped particles comprising:

a center portion; and

at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and
30 a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate

interlocking of adjacent particles in said array of shaped particles, wherein said array of shaped particles provides for treating a bone deficiency.

27. An array of shaped particles wherein said array comprises a plurality of shaped particles comprising one or more shaped particles from the group consisting of:

5 a first shaped particle comprising a center portion and at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one
10 extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles;

a second shaped particle comprising a center portion, at least two noncurved extremities, and at least three curved extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent
15 extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array; and

a third shaped particle comprising a multi-ring structure having at least
20 four curved projections wherein said projections provide for interstitial spaces between adjacent said projections, and wherein said projections facilitate interlocking of adjacent particles in said array.

28. A shaped particle for use in treating a bone deficiency wherein said particle is
25 shaped for use in an array of particles interlocked with one another, comprising:

a multi-ring structure having at least four curved projections wherein said projections provide for interstitial spaces between adjacent said projections, and wherein said projections facilitate interlocking of adjacent particles in said array.

30 29. The shaped particle of Claim 28 wherein the angles between said curved projections are equal.

30. The shaped particle of Claim 28 wherein said particle is comprised of material selected from the group consisting of a polymer, polymer/ceramic composite and polymer/glass composite.

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31. The polymer of Claim 30 wherein said polymer is selected from the group consisting of polypropylene, polylactic acid, polyglycolic acid and polycaprolactone.

10 32. A composition for use in treating a bone deficiency comprising:

a suspension material; and

a shaped particle from the group consisting of

a first shaped particle comprising a center portion and at least four tapered extremities projecting from said center portion wherein said projections provide for
15 interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles;

20 a second shaped particle comprising a center portion, at least two noncurved extremities, and at least three curved extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a transverse cross-sectional configuration, wherein said interstitial
25 spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array; and

a third shaped particle comprising a multi-ring structure having at least four curved projections wherein said projections provide for interstitial spaces between adjacent said projections, and wherein said projections facilitate interlocking of adjacent
30 particles in said array.

33. The suspension material of Claim 32 wherein said suspension material is selected from the group consisting of starch, sugar, glycerin, blood, bone marrow, autograft material, allograft material, fibrin clot and fibrin matrix.
- 5 34. The suspension material of Claim 33 wherein said suspension material is a binder capable of forming a gel.
35. The binder of Claim 34 wherein said binder is selected from the group consisting of collagen derivative, cellulose derivative, methylcellulose, hydroxypropylcellulose, hydroxypropylmethyl cellulose, carboxymethylcellulose, fibrin clot, fibrin matrix, and a biological adhesive such as cryoprecipitate.
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36. The suspension material of Claim 32 wherein said material further comprises a biological agent.
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37. The biological agent of Claim 36 wherein said agent is selected from the group consisting of a growth factor, an antibiotic, a strontium salt, a fluoride salt, a magnesium salt, a sodium salt, a bone morphogenetic factor, a chemotherapeutic agent, a pain killer, a bisphosphonate and a bone growth agent.
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38. The growth factor of Claim 37 wherein said growth factor is selected from the group consisting of platelet derived growth factor (PDGF), transforming growth factor β (TGF- β), insulin-related growth factor-I (IGF-I), insulin-related growth factor-II (IGF-II), fibroblast growth factor (FGF), beta-2- microglobulin (BDGF II) and bone morphogenetic protein (BMP).
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39. The antibiotic of Claim 37 wherein said antibiotic is selected from the group consisting of tetracycline hydrochloride, vancomycin, cephalosporins, and aminoglycocides such as tobramycin and gentamicin.
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40. The bone morphogenetic factor of Claim 37 wherein said factor is selected from the group consisting of proteins of demineralized bone, demineralized bone matrix (DBM), bone protein (BP), bone morphogenetic protein (BMP), osteonectin, osteocalcin and osteogenin.

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41. The chemotherapeutic agent of Claim 37 wherein said agent is selected from the group consisting of cis-platinum, ifosfamide, methotrexate and doxorubicin hydrochloride.

10 42. The pain killer of Claim 37 wherein said pain killer is selected from the group consisting of lidocaine hydrochloride, bipivacaine hydrochloride, and non-steroidal anti-inflammatory drugs such as ketorolac tromethamine.

15 43. The composition of Claim 32 which further includes a clotting factor composition.

44. The clotting factor composition of Claim 43 wherein said clotting factor composition comprises fibrinogen, thrombin and Factor XIII.

20 45. A method to treat a bone deficiency comprising the step of:

applying a shaped particle to a bone deficiency wherein said shaped particle is selected from the group consisting of

25 a first shaped particle comprising a center portion and at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles;

30 a second shaped particle comprising a center portion, at least two noncurved extremities, and at least three curved extremities projecting from said center

portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array; and

a third shaped particle comprising a multi-ring structure having at least four curved projections wherein said projections provide for interstitial spaces between adjacent said projections, and wherein said projections facilitate interlocking of adjacent particles in said array.

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46. A method to treat a bone deficiency comprising the steps of:

combining a shaped particle with a suspension material wherein said particle is selected from the group consisting of

a first shaped particle comprising a center portion and at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles;

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a second shaped particle comprising a center portion, at least two noncurved extremities, and at least three curved extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array; and

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a third shaped particle comprising a multi-ring structure having at least four curved projections wherein said projections provide for interstitial spaces between adjacent said projections, and wherein said projections facilitate interlocking of adjacent particles in said array; and

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applying said combination to a bone deficiency.

47. A kit for the treatment of a bone deficiency comprising:

a suspension material; and

5 multiple first shaped particles and multiple second shaped particles wherein said first and second particles are shaped for use in an array of particles interlocked with one another and wherein said particles are selected from the group consisting of

a first shaped particle comprising a center portion and at least four tapered
10 extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said
15 array of shaped particles;

a second shaped particle comprising a center portion, at least two noncurved extremities, and at least three curved extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite
20 point, a length, and a transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array; and

a third shaped particle comprising a multi-ring structure having at least four curved projections wherein said projections provide for interstitial spaces between
25 adjacent said projections, and wherein said projections facilitate interlocking of adjacent particles in said array.

48. The kit of Claim 47 wherein said multiple first and said multiple second shaped particles are composed of different materials.

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49. The kit of Claim 48 wherein said different materials are selected from the group consisting of ceramic, calcium sulphate, bioactive glass, polymer, polymer/ceramic composite, and polymer/glass composite.

5 50. The kit of Claim 47 further comprising a biological agent.

51. The kit of Claim 47 further comprising allograft material.

52. The kit of Claim 47 further comprising a clotting factor composition.

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53. The clotting factor composition of Claim 52 wherein said clotting factor composition comprises fibrinogen, thrombin and Factor XIII.

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54. The kit of Claim 47 further comprising a bowl container for said multiple first and multiple second particles and a delivery tool.

55. The delivery tool of Claim 54 wherein said delivery tool is selected from the group consisting of a spoon, a spatula, a scoop, a tweezer, forceps, a knife, a hemostat, a syringe, a pipette, a cup and a ladle.

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56. The bowl container of Claim 54 wherein said bowl is used for mixing said multiple first and multiple second particles and said suspension material.

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57. The kit of Claim 50 further comprising a bowl container for said multiple first and multiple second particles and a delivery tool.

58. The delivery tool of Claim 57 wherein said delivery tool is selected from the group consisting of a spoon, a spatula, a scoop, a tweezer, forceps, a knife, a hemostat, a syringe, a pipette, a cup and a ladle.

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59. The bowl container of Claim 59 wherein said bowl is used for mixing said multiple first and multiple second particles, said suspension material, and said biological agent.

5 60. A shaped particle for use in treating a bone deficiency wherein said particle is shaped for use in an array of particles interlocked with one another, comprising:

a center portion;

at least two noncurved extremities; and

at least three curved extremities projecting from said center portion

10 wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array.

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61. A method for manufacturing a shaped particle of calcium sulphate dihydrate comprising the steps of:

making a shaped particle of calcium sulphate dihydrate;

heating said particle; and

20 applying water to said particle.

62. A method for manufacturing a shaped particle of calcium sulphate dihydrate comprising the steps of:

making a shaped particle of calcium sulphate dihydrate;

25 heating in the presence of pressure and moisture said particle of calcium sulphate dihydrate to convert said particle to α -calcium sulphate hemihydrate partially or in full; and

applying water to said particle to convert said α -calcium sulphate hemihydrate to said calcium sulphate dihydrate.

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63. A method for manufacturing a shaped particle of calcium sulphate dihydrate comprising the steps of:

making a shaped particle of calcium sulphate dihydrate;

heating in the presence of pressure and moisture said particle of calcium

5 sulphate dihydrate to convert said particle to β -calcium sulphate hemihydrate partially or in full; and

applying water to said particle to convert said β -calcium sulphate hemihydrate to said calcium sulphate dihydrate.

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